

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

**On Appeal to the Board of
Appeals and Interferences**

Appellant(s) : Robert A. LEVINE et al.

Examiner: Henry M. Johnson, III

Serial No. : 10/523,096

Art Unit: 3739

Filed : August 31, 2005

For : CARDIAC DEVICES AND METHODS FOR MINIMALLY
INVASIVE REPAIR OF ISCHEMIC MITRAL REGURGITATION

Confirmation No.: 8398

AMENDED BRIEF ON APPEAL

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United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDED BRIEF ON APPEAL

On May 12, 2008, the U.S. Patent and Trademark Office (the "Patent Office") received a Notice of Appeal and a Pre-Appeal Brief Request for Review and Arguments ("Notice") in response to the final rejection of claims 1, 2 and 56-67 (pending in the present application) contained in the Final Office Action issued by the U.S. Patent and Trademark Office (the "Patent Office") on January 11, 2008 and in view of the Advisory Action dated May 2, 2008 in the above-identified patent application. The Notice dated July 28, 2008 indicated that a Pre-Appeal Brief Conference has been held and that the application remains under appeal because there is at least one actual issue for appeal. The Notice further indicated that Applicants should proceed with the appeal to the Board of Patent Appeals and Interferences.

Applicants filed a Brief on Appeal with the Patent Office on August 28, 2008, and received from the Patent Office a Notification of Non-Compliant Appeal Brief dated September 24, 2008. In response to the Notification of Non-Compliant Appeal Brief, Applicants submit this Amended Brief on Appeal, in which separate headings for the arguments for claims 64-66 and claim 67 are provided. Applicants believe that this brief is in full compliance with 37 C.F.R. § 41.37(c).

Pending claims 1 and 56-67 of the present application were finally rejected. Thus, in accordance with 37 C.F.R. § 41.37, this brief is being submitted in support of the appeal of the rejection of pending claims 1, 2 and 56-67. For at least the reasons set forth below, the rejection of pending claims 1, 2 and 56-67 should be reversed.

I. REAL PARTY IN INTEREST

The real party in interest is The General Hospital Corporation, Boston, Massachusetts. The General Hospital Corporation is the assignee of the entire right, title and interest in the present application.

II. RELATED APPEALS AND INTERFERENCES

Appellants and the Appellants' legal representatives are unaware of any appeals or interferences related to the present application which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1, 2 and 56-67 are under consideration in the above-referenced application, all of which have been rejected.

In particular, claim 60 stands finally rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Claims 1, 2, 56 and 57 stand finally rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,643,248 issued to Yoon (the “Yoon Patent”). Claims 1, 58, 59, 62 and 63 stand finally rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,957,863 issued to Koblish et al. (the “Koblish Patent”). Claim 61 stands finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Koblish Patent. Claims 64-66 stand finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Yoon Patent, and further in view of U.S. Patent No. 6,626,899 issued to Houser et al. (the “Houser Patent”). Claim 67 stands finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Yoon Patent, and further in view of U.S. Patent Application Publication No. US 2002/0173811 to Tu et al. (the “Tu Publication”).

Appellants appeal from the rejections of all pending claims 1, 2 and 56-67. A copy of all of the pending claims is attached hereto in the Appendix, along with a copy of the un-entered amendment to claim 1, as discussed herein below.

IV. STATUS OF AMENDMENTS

In the Response to Final Office Action dated April 11, 2008, independent claim 1 had been amended merely to remove a minor informality and not for any reason relating to patentability thereof, and new claims 68 and 69 had been added to cover certain exemplary embodiments of Appellants' invention, support being found in the originally-filed specification and drawings. In the Advisory Action, the Examiner indicated that the amendment to claim 1 and new claims 68 and 69 would not be entered. However, Appellants respectfully assert that at least the amendment to independent claim 1 should have been entered as being made only for consistency purposes and would not necessitate a new search and would reduce the issues for appeal.

Attached hereto in the Appendix following the listing of pending claims is a copy of the un-entered amendment to independent claim 1 and new claims 68 and 69, which depend therefrom, as presented in the amendment filed on April 11, 2008. Appellants respectfully request entry thereof and consideration thereof by the Board.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Currently-pending independent claim 1 relates to an apparatus for treating atrioventricular valve regurgitation.

In particular, independent claim 1 recites: an apparatus for treating atrioventricular valve regurgitation (see, e.g., original specification, Abstract and paragraphs [0009] and [0018]), comprising:

a cutting arrangement configured to sever at least one chord (see, e.g., original specification, paragraphs [0009], [0011] to [0013], [0015], [0018] and [0035] to [0041], and Figures 1C, 3B, 5 and 6A-6C) attaching an atrioventricular leaflet to a internal cardiac muscle (see, e.g., original specification, paragraphs [0009], [0011], [0018] and [0035], and Figure 1C);

a positioning catheter configured to position the cutting instrument proximate the at least one chord (see, e.g., original specification, paragraphs [0012], [0013], [0016], [0018], [0043] and [0044], and Figures 3B, 4A, 4B, 7A and 7B); and

a grasping arrangement configured to at least partially constrain a movement of the at least one chord relative to the catheter (see, e.g., original specification, paragraphs [0013], [0036], [0037] and [0039] to [0041], and Figures 4A and 4B),

wherein the catheter comprises an opening through which the cutting arrangement can be provided to sever the at least one chord (see, e.g., original specification, paragraphs [0013], [0037] and [0039], and Figures 4A and 4B).

Claim 60, which depends from independent claim 1 and is argued separately, recites the apparatus of claim 58 (see, e.g., original specification, paragraphs [0037] to [0039], and Figures 4A and 4B), wherein a distal end of the wire is

configured at an acute angle relative to a surface of the opening (see, e.g., original specification, paragraph [0037] and Figure 4A).

Claim 61, which also depends from claim 1 and is argued separately, recites the apparatus of claim 58 (see, e.g., original specification, paragraphs [0037] to [0039], and Figures 4A and 4B), wherein the wire comprises a shape-memory material (see, e.g., original specification, paragraphs [0038], [0039], [0042] and [0047]).

VI. GROUND OF REJECTION TO BE REVIEWED

The grounds of rejection on appeal to be reviewed are as follows:

A. Whether the Examiner failed to establish a *prima facie* case that dependent claim 60, which stands finally rejected under 35 U.S.C. § 112, second paragraph, is indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Appellants regard as their invention.

B. Whether the Examiner failed to establish a *prima facie* case that claims 1, 2, 56 and 57, which stand finally rejected under 35 U.S.C. § 102(b), are unpatentable over the Yoon Patent.

C. Whether the Examiner failed to establish a *prima facie* case that claims 1, 58, 59, 62 and 63, which stand finally rejected under 35 U.S.C. § 102(b), are unpatentable over the Koblish Patent.

D. Whether the Examiner failed to establish a *prima facie* case that dependent claim 61, which stands finally rejected under 35 U.S.C. § 103(a), is unpatentable over the Koblish Patent.

E. Whether the Examiner failed to establish a *prima facie* case that dependent claims 64 to 66, which stand finally rejected under 35 U.S.C. § 103(a), is unpatentable over the Yoon Patent, and further in view of the Houser Patent, and that dependent claim 67, which stands finally rejected under 35 U.S.C. § 103(a), is unpatentable over the Yoon Patent, and further in view of the Tu Publication.

VII. ARGUMENTS

1. Primary Prior Art relied on by the Examiner

A. The Yoon Patent

With respect to claims 1, 2, 56 and 57, the Examiner relies on the Yoon Patent for maintaining the final rejections of these claims.

The Yoon Patent “relates to medical procedures and instruments and, more particularly, to a medical instrument that prevents probes from applying excessive force to anatomical tissue structures by retracting or protruding the probes.” (Yoon Patent, col. 1, Ins. 8-12).

B. The Koblish Patent

With respect to claims 1, 58, 59 and 61-63, the Examiner relies on the Koblish Patent for maintaining the final rejections of these claims.

The Koblish Patent describes “[a] deflectable biopsy catheter for obtaining a tissue sample from a body cavity of a patient comprising . . . a pair of biopsy jaws coupled to the distal end of the catheter shaft and having first and second opposed free cutting surfaces exposable for contact with a selected area of tissue within the patient’s body cavity and movable with respect to each other to cut a tissue sample from the selected area of tissue.” (Koblish Patent, Abstract).

C. The Houser Patent

With respect to dependent claims 64-66, the Examiner relies on the Yoon Patent in combination with the Houser Patent for maintaining the final rejections of these claims.

The Houser Patent relates to methods and apparatus for treating valvular disease with a catheter inserted into a patient’s cardiac chambers, the catheter having an end effector for modifying cardiac structures, including valve leaflets and support structure. (Houser Patent, col. 1, lns. 14-19).

D. The Tu Publication

With respect to dependent claim 67, the Examiner relies on Yoon Patent in combination with the Tu Publication for maintaining the final rejection of these claims.

The Tu Publication “relates to an endoluminal catheter and methods for removing a defective valve and adapted for implantation of a valvular prosthesis.” (Tu Publication, paragraph [0001]).

2. Relevant Case Law and Procedure(s)

35 U.S.C. § 112, Second Paragraph Case Law

35 U.S.C. § 112, Second Paragraph recites “the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112, Second Paragraph. The Manual of Patent Examining Procedures, §2173.02 states that the “The examiner’s focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available.” Manual of Patent Examining Procedures, §2173.02. This section of the Manual of Patent Examining Procedures further recites:

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A)The content of the particular application disclosure; (B)The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Id. “The requirement to ‘distinctly’ claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles....Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.” *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004).

35 U.S.C. § 102 Case Law

As the Board is well aware, in order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; also see *Lindeman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

35 U.S.C. § 103 Case Law

“To reject claims in an application under Section 103, an examiner must show an unrebutted *prima facie* case of obviousness.” *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998). The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

Under Section 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Indeed, to sustain a rejection under 35 U.S.C. § 103(a), there must be some teaching, other than the instant application, to alter the prior art to arrive at the claimed invention. “The problem confronted by the inventor must be considered in determining whether it would have been obvious to combine the references in order to solve the problem.” *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 679 (Fed. Cir. 1998).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the appellants (the “TSM test”). See *In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit’s application of the TSM test, see *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; see *In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007). Further, the Court underscored that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or

motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, “the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure.” *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O’Farrell*, 853 F.2d. 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in appellants’ disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. See *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

To establish obviousness, the prior art references must be evaluated as a whole for what they fairly teach and neither the references’ general nor specific teachings may be ignored. *Application of Lundsford*, 357 F.2d. 385, 389-90 (CCPA

1966). A reference must be considered for all that it teaches, not just what purportedly points toward the invention but also that which teaches away from the invention. *Ashland Oil, Inc. v. Delta Resins & Refractories*, 776 F.2d. 281, 296 (Fed. Cir. 1985).

3. Issues on Appeal

A. Dependent claim 60

Appellants respectfully assert that the Examiner failed to establish a *prima facie* case that dependent claim 60 of the above-referenced application, which stands finally rejected under 35 U.S.C. § 112, second paragraph, is indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention for at least for the reasons provided in greater detail herein below.

Claim 60 recites “[t]he apparatus of claim 58, wherein a distal end of the wire is configured at an acute angle relative to a surface of the opening.” Appellants note that claim 58 depends from claim 57, which depends from independent claim 1.

Claim 60 was finally rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, in the Final Office Action, the Examiner alleged that it is not clear how the acute angle is defined relative to the surface as the wire is essentially circular and presents multiple angles. Although Appellants addressed this rejection in the response to Final Office Action dated April 11, 2008, the Examiner did not respond to such explanation in the Advisory Action dated May 2, 2008.

Appellants respectfully assert that the subject matter of claim 60 is in no way indefinite, contrary to the contentions contained in the Final Office Action. As provided in paragraph [0037] of the specification of the above-identified application, for example, “[o]ther deformations in the wire suitable to grasp the chord 10, such as sharp to orthogonal bends or V-shapes, are possible.” (Appellants’ Specification, paragraph [0037]). Clearly, a “V-shape” deformation in the wire suitable to grasp the chord 10 defines an acute angle relative to a surface of the opening, as recited in claim 60. (See also, e.g., Fig. 4A of the original application, which shows an exemplary embodiment of a preferred flexible hook relative to a surface of the opening.)

Accordingly, Appellants respectfully assert that the subject matter recited in dependent claim 60 is certainly not indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention, and that the rejection to dependent claim 60 under 35 U.S.C. § 112, second paragraph should be withdrawn for at least these reasons. Therefore, Appellants respectfully assert that claim 60 is also allowable for at least the same reasons discussed above with respect to independent claim 1, as well as containing separately patentable subject matter. Indeed, the Examiner did not reject this claim under any 35 U.S.C. § 102 or 35 U.S.C. § 103 as being anticipated or unpatentable, respectively.

B. Claims 1, 2, 56 and 57

Appellants respectfully assert that the Yoon Patent fails to disclose the subject matter recited in independent claim 1 of the above-referenced application, and

the claims which depend therefrom, for at least for the reasons provided in greater detail herein below.

Appellants' invention, as recited in independent claim 1, relates to an apparatus for treating atrioventricular valve regurgitation, comprising, *inter alia*:

a cutting arrangement configured to sever at least one chord attaching an atrioventricular leaflet to a internal cardiac muscle;

a positioning catheter configured to position the cutting instrument proximate the at least one chord; **and**

a grasping arrangement configured to at least partially constrain a movement of the at least one chord relative to the catheter,

wherein the catheter comprises an opening through which the cutting arrangement can be provided to sever the at least one chord.

Thus, it is clear that independent claim 1 recites an apparatus for treating atrioventricular valve regurgitation which includes, *inter alia*, **a cutting arrangement and a grasping arrangement**, i.e. two different and separate arrangements. Appellants respectfully assert that the Yoon Patent does not teach or suggest, much less disclose, both a cutting arrangement and a grasping arrangement, i.e. **two different and separate arrangements**. Rather, the Yoon Patent describes a hook, which the Examiner admittedly asserts on page 3 of the Final Office Action "serves as both a grasping and cutting means" (see *Final Office Action*, p. 3, lines 6-7).

Further, the Examiner contends on page 2 of the Advisory Action that a "[b]road interpretation of [independent] claim 1 does not require separate cutting and grasping members." Advisory Action, p. 2. However, independent claim 1 clearly recites **a cutting arrangement as one arrangement and a grasping arrangement as**

another separate and distinct arrangement. Therefore, it is abundantly evident that independent claim 1 clearly recites a separate cutting arrangement and a separate grasping arrangement, contrary to the Examiner's assertion in the Advisory Action.

Moreover, the hook described in the Yoon Patent serving as both a cutting arrangement and a grasping arrangement preclude the ability to separately maneuver and adjust each of the two separate arrangements as recited in independent claim 1. Since the Yoon Patent does **not** disclose both a cutting arrangement and a grasping arrangement **as two separate and distinct arrangements**, as explicitly recited in independent claim 1, Appellants respectfully assert that the Yoon Patent does not disclose all of the elements recited in independent claim 1. Indeed, none of the other references relied on by the Examiner disclose such separate cutting arrangement and grasping arrangement.

Furthermore, claims 2, 56 and 57 depend from independent claim 1, and Appellants respectfully assert that these claims are also patentable over the Yoon Patent for at least the same reasons provided above with respect to independent claim 1.

Accordingly, Appellants respectfully assert that the subject matter recited in claims 1, 2, 56 and 57 is not disclosed in the Yoon Patent, and that the final rejections of pending claims 1, 2, 56 and 57 under 35 U.S.C. §102 as being allegedly anticipated by the Yoon Patent therefore should be withdrawn.

C. Claims 1, 58, 59, 62 and 63

Appellants respectfully assert that the Koblish Patent fails to disclose the subject matter recited in independent claim 1 of the above-referenced application, and the claims which depend therefrom, for at least for the reasons provided in greater detail herein below.

Appellants' invention, as recited in independent claim 1, relates to an apparatus for treating atrioventricular valve regurgitation, comprising, *inter alia*:

a cutting arrangement configured to sever at least one chord attaching an atrioventricular leaflet to a internal cardiac muscle;

a positioning catheter configured to position the cutting instrument proximate the at least one chord; **and**

a grasping arrangement configured to at least partially constrain a movement of the at least one chord relative to the catheter,

wherein the catheter comprises an opening through which the cutting arrangement can be provided to sever the at least one chord.

It is thus clear that independent claim 1 recites an apparatus for treating atrioventricular valve regurgitation which includes, *inter alia*, **a cutting arrangement and a grasping arrangement**, i.e. two separate and distinct arrangements. Appellants respectfully assert that the Koblish Patent does not teach or suggest, much less disclose, both a cutting arrangement and a grasping arrangement, i.e. **two separate and distinct arrangements**.

Rather, the Koblish Patent describes jaws that work together to form a cutting member. Then, the Examiner asserts (on page 3 of the Final Office Action) that the jaws of the Koblish Patent inherently grasp and cut a biopsy sample and operate via

a wire looped into the jaws, making the wire a part of the grasping member. (See *Final Office Action*, page 3, lines 13-16).

Further, the Examiner asserts (on page 2 of the Advisory Action) that a “[b]road interpretation of [independent] claim 1 does not require separate cutting and grasping members.” (Advisory Action, p. 2). However, independent claim 1 clearly recites **a cutting arrangement as one arrangement and a grasping arrangement as another, separate and distinct arrangement**. Therefore, it is abundantly evident that independent claim 1 clearly recites a separate cutting arrangement and a separate grasping arrangement, contrary to the Examiner’s assertion in the Advisory Action.

Moreover, the jaws described in the Koblish Patent serving as both a cutting arrangement and a grasping arrangement preclude the ability to separately maneuver and adjust each of the two arrangements. As the Koblish Patent does **not** disclose both a cutting arrangement and a grasping arrangement **as two separate and distinct arrangements**, as explicitly recited in independent claim 1, Appellants respectfully assert that the Koblish Patent does not disclose all of the elements recited in independent claim 1.

Furthermore, claims 58, 59, 62 and 63 depend from independent claim 1, and Appellants respectfully assert that these claims are also patentable over the Koblish Patent for at least the same reasons provided above with respect to independent claim 1.

Accordingly, Appellants respectfully assert that the subject matter recited in claims 1, 58, 59, 62 and 63 is not disclosed in the Koblish Patent. Thus, the

rejections of pending claims 1, 58, 59, 62 and 63 under 35 U.S.C. §102 as allegedly being anticipated by the Koblish Patent therefore should be withdrawn.

D. Dependent claim 61

Appellants respectfully assert that the Koblish Patent fails to teach or suggest the subject matter recited in dependent claim 61 of the above-referenced application for at least for the reasons provided in greater detail herein below.

Claim 61 recites “[t]he apparatus of claim 58, wherein **the wire comprises a shape-memory material.**” Appellants note that claim 58 depends from claim 57, which depends from independent claim 1. Thus, for at least the same reasons as indicated herein above with reference to claim 1, claim 61 is believed to be patentable over the Koblish Patent.

Further, with respect to the rejection of dependent claim 61 under § 103(a), the Examiner admits that the Koblish Patent does not teach using a shape-memory material as recited in claim 61, but contends that a skilled artisan would be motivated to shape memory materials to achieve a desired shape as the use of these materials is allegedly well known and obvious. (See *Final Office Action*, p. 4, Ins. 1-5.)

However, Appellants respectfully assert that one of ordinary skill in the art at the time the invention was made would not have been motivated to use a wire comprising shape-memory material as recited in claim 61 and indeed would have been discouraged from doing so. In particular, as wire strands 70, 72 in the Koblish Patent are used to connect the proximal extensions of jaws 30, 32 to actuation wire 60 (see,

e.g. the *Koblish Patent*, Fig. 2 and col. 5, Ins. 3-19), there would have been no motivation to use wire comprising shape-memory material, which is believed to be more costly than other suitable wires, and there would be no reason to do that in the *Koblish Patent*. Indeed, as it is believed to be more costly to use wire comprising shape-memory material than other suitable wires, one skilled in the art at the time the invention was made would actually be discouraged from using such shape material as opposed to less costly suitable alternatives without a reason or motivation to do so. Indeed, the Examiner has not provided any further support or reference in support of his allegation.

Accordingly, in addition to the reasons discussed above with respect to independent claim 1, from which claim 61 depends, Appellants respectfully assert that the subject matter claimed in dependent claim 61 would not have been obvious to one of ordinary skill in the art at the time the invention was made for at least the reasons discussed herein as well, and that the rejection of claim 61 under 35 U.S.C. § 103(a) should be withdrawn.

E. Dependent claims 64 to 66

Appellants respectfully assert that the Examiner failed to establish a *prima facie* case that dependent claims 64 to 66, which stand finally rejected under 35 U.S.C. § 103(a), is unpatentable over the Yoon Patent, and further in view of the Houser Patent for at least for the reasons provided in greater detail herein below.

The Examiner admittedly relies on the Yoon Patent for the recitations of independent claim 1, and then contends that the Houser Patent discloses the additional

limitations recited in dependent claims 64-66. However, as discussed above with respect to independent claim 1, Appellants respectfully assert that the Yoon Patent fails to teach, suggest or disclose the subject matter recited in independent claim 1 and the claims which depend therefrom for at least the reasons discussed above. In addition, Appellants respectfully assert that the Houser Patent fails to cure the deficiencies of the Yoon Patent to the subject matter recited in independent claim 1 and the claims which depend therefrom, as contended by the Examiner. Accordingly, Appellants respectfully assert that the subject matter recited in dependent claims 64-66 is not taught or suggested in the Yoon Patent in view of the Houser Patent.

F. Dependent claim 67

Appellants respectfully assert that the Examiner failed to establish a *prima facie* case that dependent claim 67, which stands finally rejected under 35 U.S.C. § 103(a), is unpatentable over the Yoon Patent, and further in view of the Tu Publication for at least for the reasons provided in greater detail herein below.

The Examiner admittedly relies on the Yoon Patent for the recitations of independent claim 1, and then contends that the Tu Publication discloses the additional limitations recited in dependent claim 67. However, as discussed above with respect to independent claim 1, Appellants respectfully assert that the Yoon Patent fails to teach, suggest or disclose the subject matter recited in independent claim 1 and the claims which depend therefrom for at least the reasons discussed above. In addition, Appellants respectfully assert that the Tu Publication fails to cure the deficiencies of the Yoon Patent to the subject matter recited in independent claim 1 and claim 67, which

depends therefrom, as contended by the Examiner. Accordingly, Appellants respectfully assert that the subject matter recited in dependent claim 67 is not taught or suggested in the Yoon Patent in view of the Tu Publication.

Accordingly, in addition to the reasons discussed above with respect to independent claim 1, from which claims 64-67 depend, Appellants respectfully assert that the subject matter recited in dependent claims 64-67 would not have been obvious to one of ordinary skill in the art at the time the invention was made. Appellants thus respectfully assert that dependent claims 64-67 are also allowable for at least the same reasons discussed above with respect to independent claim 1, as well as containing separately patentable subject matter.

4. Conclusion

For at least the reasons indicated above, Appellants respectfully assert that the invention recited in the presently rejected claims of the present application, as discussed above, is new, non-obvious and useful. Reversal of the Examiner's rejections of the claims is therefore respectfully requested.

Respectfully submitted,

Dated: October 15, 2008

By:



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CLAIMS APPENDIX

Claims as currently pending:

1. An apparatus for treating atrioventricular valve regurgitation, comprising:
 - a cutting arrangement configured to sever at least one chord attaching an atrioventricular leaflet to a internal cardiac muscle;
 - a positioning catheter configured to position the cutting instrument proximate the at least one chord; and
 - a grasping arrangement configured to at least partially constrain a movement of the at least one chord relative to the catheter,wherein the catheter comprises an opening through which the cutting arrangement can be provided to sever the at least one chord.
2. The apparatus of claim 1, wherein the cutting instrument comprises a blade having a cutting edge width that is approximately the same size as a diameter of the at least one chord.
56. The apparatus of claim 1, wherein the cutting arrangement is further configured to sever at least one chord while the grasping arrangement is at least partially constraining a movement of the at least one chord.
57. The apparatus of claim 1, wherein the grasping arrangement comprises a grasping member configured to slide along a longitudinal direction relative to an extension axis of the catheter.

58. The apparatus of claim 57, wherein the grasping member comprises a wire.

59. The apparatus of claim 58, wherein a distal end of the wire is curved.

60. The apparatus of claim 58, wherein a distal end of the wire is configured at an acute angle relative to a surface of the opening.

61. The apparatus of claim 58, wherein the wire comprises a shape-memory material.

62. The apparatus of claim 1, wherein the grasping arrangement comprises at least one pincer member which is rotatably coupled to the catheter and which is configured to surround at least a portion of the at least one chord.

63. The apparatus of claim 1, wherein the grasping arrangement comprises at least two pincer members which are rotatably coupled to the catheter and which are configured to surround at least a portion of the at least one chord.

64. The apparatus of claim 1, further comprising a stabilizing arrangement configured to at least partially constrain a motion of the catheter relative to a location within a chamber of a heart.

65. The apparatus of claim 64, wherein the stabilizing arrangement comprises an extendable member which is configured to contact the location within the chamber.

66. The apparatus of claim 65, wherein the stabilizing arrangement comprises a shape memory material.

67. The apparatus of claim 1, further comprising a second catheter configured to advance the positioning catheter toward the at least one chord.

Un-entered amendment to claim 1 and new claims 68 and 69 filed in the Response to Final Office Action dated April 11, 2008:

1. (Currently Amended) An apparatus for treating atrioventricular valve regurgitation, comprising:

a cutting arrangement configured to sever at least one chord attaching an atrioventricular leaflet to a internal cardiac muscle;

a positioning catheter configured to position the cutting instrument arrangement proximate the at least one chord; and

a grasping arrangement configured to at least partially constrain a movement of the at least one chord relative to the catheter,

wherein the catheter comprises an opening through which the cutting arrangement can be provided to sever the at least one chord.

68. (New) The apparatus of claim 1, wherein the cutting arrangement is entirely separate from the grasping arrangement.

69. (New) The apparatus of claim 1, wherein each of the cutting arrangement and the grasping arrangement is separately maneuverable and adjustable.

EVIDENCE APPENDIX

Nothing to include

RELATED PROCEEDINGS APPENDIX

Nothing to include